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10/696,846	10/31/2003	Farid Bruce Khalili	622/20	8064
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GIBSON & DERNIER LLP 900 ROUTE 9 NORTH SUITE 504 WOODBRIDGE, NJ 07095			EXAMINER	
			PELLEGRINO, BRIAN E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/696,846	<b>Applicant(s)</b> KHALILI, FARID BRUCE
	<b>Examiner</b> Brian E. Pellegrino	<b>Art Unit</b> 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 April 2010.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 3-5,8-10,18 and 20-27 is/are pending in the application.  
 4a) Of the above claim(s) 4 and 5 is/are withdrawn from consideration.  
 5) Claim(s) 3,8-10,18,20-24,26 and 27 is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) 25 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 16 April 2010 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claim 17 have been considered but are moot in view of the new ground(s) of rejection. In response to comments regarding the rejection over Mazda in view of other references, comments were made against Mazda. The Examiner would like to comment on the argument that it is not evident from Mazda that the second base component has a raised wall since no translation was provided by the Examiner. First the Examiner will provide a translation with the current action, however, the translation is a moot point in seeing that the drawing in Mazda, particularly Figure 5 that there is a raised wall portion evident in the central portion of the plates with a sloping surface 31. Therefore, Mazda clearly discloses the raised wall portion on the base component as claimed. Applicant then argues that the teaching references fail to disclose the new limitation of the slot in the base component along with the middle component. The argument is moot in view of the teaching of Keller of which clearly discloses the use of a slot in a base component to engage a slot in a middle component of a spinal implant such that it retains the two pieces together and prevents vertical movement or separation.

### ***Drawings***

The drawings were received on 4/16/10. These drawings are acceptable.

***Specification***

The amendment to the specification filed 4/16/10 has been entered.

***Claim Objections***

Claim 27 is objected to because of the following informalities: the claim recites the "middle component comprises a spring retention groove extending across a length of the base component..... It appears the middle component has the groove, but the clause that it extends across the length of the base component is confusing and is understood that Applicant meant the groove extends across a surface of the middle component which is disposed over or lies above the base component. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 21, the "second base component has a raised wall to slidingly receive the second side of the middle component" was recited and depend from claim 17 which already recited the second base component "slideably receives the second side of the middle component". However, claim 17 recited the two

corresponding components couple together via the recited "slot with edges in each of the middle and second base components extending linearly from anterior to posterior" establishing a particular orientation. Does this raised wall extend in the same direction to slidingly receive the middle component? Is it forming the slot? Additionally, claim 24 further recites a "side slot" which already had a slot recited in claim 17. Claim 24 appears to be a double inclusion of the "slot" because it introduces the same element or feature already recited in claim 17, see MPEP 2173.05 (o). Where a claim directed to a device can be read to include the same element twice, the claim may be indefinite. Ex parte Kristensen, 10 USPQ2d 1701 (Bd. Pat. App. & Inter. 1989). Thus it is not clear what Applicant meant. Is this some additional slot?

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3,8,9,17,18,20,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazda (WO 94/04100) in view of Alfaro et al. (2001/32017) and Michelson (6120503) and Keller et al. (EP 1344508). Mazda shows (Fig. 5) a spinal implant with a first base component **25**, a second base component **26**, and a middle component **22** having a convex side **9**. The first base component having a second side that comprises a concave portion **12** with a constant radius to engage the convex surface of the middle component. As seen in Fig. 5, there are a plurality of sharpened teeth **17** and are positioned on each side of the top and bottom components for

**engaging vertebrae.** However, Mazda fails to disclose the surface for engaging vertebrae includes a pair of concentric raised circular portions stacked on one another with angled sidewalls that taper inwardly in the direction towards the base component and that each the middle component with the second base component have a slot with edges extending linearly from anterior to posterior. Alfaro et al. teach (Figs. 1,11) that the vertebral engaging surface of the implant includes a pair of circular raised portions stacked on top of one another for the top and bottom surfaces of the spinal implant.

Michelson teaches (Figs. 9,11) stacked bone engagement portions with angled sidewalls that taper in the direction towards the surface of the base component.

Michelson additionally shows (Fig. 13E) that the cross-section of the bone penetrating portions that are stacked can be tapered inwardly. Michelson further teaches that the stacked and angled inward tapering provides a force as being inserted into vertebrae, col. 8, lines 45-54,63,64. It would have been obvious to one of ordinary skill in the art to incorporate the circular stacked raised portions as taught by Alfaro et al. with the spinal implant of Mazda since it would complement the spinal space more naturally, see Alfaro (paragraph 11). Further it would have been obvious to additionally modify the stacked raised portions to be tapered inwardly as taught by Michelson with the spinal implant of Mazda as modified by Alfaro et al. such that it firmly engages the vertebrae and assures it is properly seated within the vertebral bones. Keller et al. teach (Fig. 3) that a middle component **10** and the second or bottom base component **8** each have a slot extending linearly from anterior to posterior. It would have been obvious to one of ordinary skill in the art to incorporate slots in each of the second or bottom base component with the

middle component as taught by Keller et al. in the prosthesis of Mazda as modified with Michelson and Alfaro such that it prevents the components from slipping in a vertical direction when implanted in the patient. Regarding claim 8, it can be seen the middle component is removably or slidably received in slot **28** such that the convex portion extends above the "generally" flat portion of the inner second side of the second base component. It can be construed that grooves in the plates for the screw in teeth lie below the flat surface and surround the convex component. With respect to claim 9, it can be seen in Fig. 2 of Mazda that the center of the middle component is closer to one edge than the other. Regarding claim 18, Fig. 6 of Mazda show the teeth are positioned near the periphery and Alfaro teaches the stacked circular raised portions are centrally located. With respect to claim 20, it can be seen (Fig. 3) that the incorporated raised portions taught by Alfaro et al. are shown with flat top surfaces. Regarding claim 21, it can be seen (Fig. 5) of Mazda that the inner surface of the base component is raised and slidingly receives the middle component.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazda (WO 94/04100) in view of Alfaro et al. (2001/32017) and Michelson '503 and Keller et al. (EP 1344508) as applied to claim 17 above, and further in view of Khandkar et al. (2004/133281). Mazda is explained above. However, Mazda fails to disclose the middle component varies in height from posterior to anterior edges. Khandkar et al. teach (Fig. 8) that middle component **42** varies in height from posterior to anterior edges to provide limited amount of axial rotation and translation, Paragraph 73. It would have been obvious to one of ordinary skill in the art to modify the middle component to be

varied in height as taught by Khandkar et al. in the spinal implant of Mazda modified with Alfaro et al. and Michelson and Keller et al. such that it limits movement in a patient that can only have limited motion.

Claims 22,23,24,27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazda (WO 94/04100) in view of Alfaro et al. (2001/32017) and Michelson '503 and Keller et al. (EP 1344508) as applied to claim 21 above, and further in view of Errico et al. (6989032).

Mazda as modified with Alfaro and Michelson and Keller is discussed above. However, Mazda in view of Alfaro and Michelson fail to disclose the raised portion has apertures and the middle component is secured via a clipping element. Errico et al. show (Figs. 1i,1j) base component with raised portion **40** and apertures **44** to secure a middle component **31** using clipping elements **46**. It would have been obvious to one of ordinary skill in the art to incorporate a plurality of apertures in the raised portion of the plate and use clipping elements as taught by Errico et al. with spinal implant of Mazda as modified with Alfaro and Michelson and Keller et al. such that the components cannot become dislodged or misaligned. Regarding claim 27, Errico teaches (Fig. 10o) that a groove can extend across a length of a middle component to receive a clip element.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazda (WO 94/04100) in view of Alfaro et al. (2001/32017) and Michelson '503 and Keller et al. as applied to claim 17 above, and further in view of Buettner-Janz et al. (4759766).

Mazda as modified with Alfaro and Michelson is discussed above. However, Mazda in view of Alfaro and Michelson and Keller fail to disclose the middle component have a circumferential groove and a rim disposed around the concave portion of the base component. Buettner-Janz show (Fig. 2) a middle component **4** of a spinal implant with a circumferential groove **5** that is formed between the middle component for matching with rim **2** of base components shown in Figs. 1,3. Buettner-Janz teach the groove provides a guide for preventing over rotation and possible slip out of middle component, Col. 5, lines 6-11. It would have been obvious to one of ordinary skill in the art to incorporate a circumferential groove about the middle component of Mazda's spinal implant as modified with Alfaraao and Michelson and Keller per the teaching of Buettner-Janz such that over rotation is prevented and any risk of slip out.

#### ***Allowable Subject Matter***

Claim 25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700  
/Brian E Pellegrino/  
Primary Examiner, Art Unit 3738